APPROVEDCHAPTERAPRIL 9, 2024610BY GOVERNORPUBLIC LAW

STATE OF MAINE

IN THE YEAR OF OUR LORD

TWO THOUSAND TWENTY-FOUR

S.P. 996 - L.D. 2282

An Act to Provide Greater Transparency About the Cost of Insulin and to Promote the Availability of Low-cost Insulin in the State

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §8731, sub-§1-B is enacted to read:

1-B. Category of insulin. "Category of insulin" means rapid-acting, short-acting, intermediate-acting, long-acting and premixed insulin for which at least 2 licenses have been issued by the federal Food and Drug Administration and are actively marketed pursuant to such licensure in a category.

Sec. 2. 22 MRSA §8731, sub-§2-A is enacted to read:

2-A. Insulin. "Insulin" has the same meaning as in Title 32, section 13786-D, subsection 1, paragraph A and includes insulin or an insulin pen that is licensed under the federal Public Health Service Act, 42 United States Code, Section 262(a) or 262(k).

Sec. 3. 22 MRSA §8732, sub-§3 is enacted to read:

3. Notification by manufacturers of wholesale acquisition cost for insulin. No later than February 15th of each year, a manufacturer of insulin shall notify the organization of the wholesale acquisition cost per pricing unit for the insulin produced by the manufacturer in each category of insulin.

Sec. 4. 32 MRSA §13800-D, sub-§2, as enacted by PL 2021, c. 303, §5, is amended to read:

2. Exception. A manufacturer that is a nonprofit organization or whose aggregate total of insulin sold, delivered or distributed in this State does not exceed 500,000 units of insulin in the year in which a registration fee under subsection 1 is due is not required to pay the registration fee. To qualify for the exception under this subsection, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due, in a manner determined by the board, that the aggregate total of insulin produced by the manufacturer that was sold, delivered or distributed within this State in the year in which the manufacturer seeks to claim the exception did not exceed 500,000 units. The board may adopt rules to implement this section. Rules adopted

pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.